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2023 Drug Approvals: After a Down Year, FDA Signs Off on a Bounty of New Meds, Including 7 From Pfizer + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

3

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2023 Drug Approvals: After a Down Year, FDA Signs Off on a Bounty of New Meds, Including 7 From Pfizer

Fierce Pharma reported:

> In 2022, fueled by its powerhouse COVID products, Pfizer became the first company in the history of the biopharma industry to top $100 billion in annual revenue. What would the New York drugmaker do for an encore?
>
> In 2023, Pfizer went from generating the most sales in the industry to gaining the most approvals.
>
> With seven FDA nods in 2023, Pfizer had more than double that of any other company. It's also more than twice as many as every drugmaker over each of the last three years. You need to go back to 2019, when Novartis scored six approvals, to find a company that approached what Pfizer accomplished in 2023.

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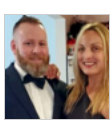
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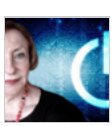
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Pfizer's splurge included four approvals in a dizzying five weeks in May and June. And all but one of the seven products has been pegged by analysts as a potential blockbuster.

The new Pfizer products cover a wide swath of indications between multiple myeloma drug Elrexfio, OPKO-partnered growth failure treatment Ngenla, first-in-class alopecia therapy Litfulo, RSV vaccine Abryvso and COVID-19 antiviral Paxlovid, which gained a full approval.

Moderna Jumps on Oppenheimer Upgrade, 2025 Sales Growth Goal

Reuters reported:

Moderna (MRNA.O) shares gained nearly 14% on Tuesday as brokerage Oppenheimer upgraded the stock to "outperform" and the vaccine maker's CEO reiterated the company's goal of achieving sales growth in 2025.

Shares of the company slumped nearly 45% in 2023, marking their worst annual performance to date, weighed down by weak sales of its COVID-19 vaccine.

"With the expected launch of our RSV (respiratory syncytial virus) vaccine candidate in 2024 and potential launch of our flu/COVID combination vaccine as early as 2025, we believe Moderna will experience sales growth in 2025," CEO Stéphane Bancel said in a letter to shareholders.

McKinsey to Pay $78 Million U.S. Opioid Settlement With Health Insurers, Company Benefit Plans

The Hill reported:

Consulting giant McKinsey & Company agreed to a $78 million settlement in a case over its role in advising opioid manufacturers to design misleading marketing campaigns.

A group of U.S. health insurers and company benefit plans, referred to in court documents as third-party payors, alleged in the suit that the firm helped add fuel to the fire in the opioid abuse epidemic by advising drug manufacturers such as Purdue Pharma in crafting deceptive marketing campaigns for opioids.

The potential settlement, the agreement to which was filed Friday, still requires a judge's approval. If presiding judge Charles R. Breyer, district judge for the Northern District of California signs off on the settlement, McKinsey has two weeks from the approval date to pay $78 million to the plaintiffs by wire.

The settlement comes two years after McKinsey paid $573 million to 49 state attorneys general, in Washington, DC, and five territories in a similar case.

The settlement also comes more than a year after the House Oversight Committee released a report detailing McKinsey's conflicts of interest in taking contracts for the Food and Drug Administration (FDA) while working for opioid manufacturers. The report also alleged McKinsey used its government consulting work to attract more business from drug manufacturers and attempt to influence government officials to clients' advantage.

Nutramigen Powder Baby Formula Recalled for Fear of Bacterial Contamination

The Hill reported:

Reckitt/Mead Johnson Nutrition (MJN) on Sunday recalled some batches of its Nutramigen Hypoallergenic Infant Formula Powder, a product marketed toward infants with milk allergies.

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The recall affects Nutramigen Powder 12.6 and 19.8-ounce cans sold in the United States. MJN said in an announcement that the recall was due to a "possibility of contamination with Cronobacter sakazakii."

The recalled product was manufactured in June and distributed between June and August. MJN posted product batch codes for the affected cans, which have a "use by" date of Jan. 1, 2025.

Big Pharma Is Raising Prices This Month

Newsweek reported:

Americans are set to see some major price hikes on their everyday medications in 2024. Roughly 500 drugs will increase in cost, according to healthcare research firm 3 Axis Advisors. That includes 140 different brands of drugs and their different doses, the company's data showed.

The price increase arrives as President Joe Biden plans to unveil 10 historically pricy drugs at reduced rates later on in the year. His administration's Inflation Reduction Act allows Medicare to negotiate lower prices, beginning in 2026.

Last year, various companies cut prices for insulin to avoid penalties under the 2021 American Rescue Plan Act, but big pharma companies tend to jolt prices up in the new year to keep in line with inflationary pressures.

Pfizer will have the most price increases this month, with more than a quarter of all increases for January, the report found. After Pfizer, Baxalta will be raising prices the most, with 53 drugs affected. Sanofi is also increasing prices by 9% on drugs for people with typhoid fever, as well as rabies and yellow fever vaccines.

Judge Certifies Johnson & Johnson Shareholder Class Action Over Talc Disclosures

Reuters reported:

A federal judge said Johnson & Johnson (JNJ.N) shareholders may pursue as a class action their lawsuit accusing the company of fraudulently concealing how its talc products were contaminated by cancer-causing asbestos.

U.S. District Judge Zahid Quraishi in Trenton, New Jersey, on Friday allowed shareholders from Feb. 22, 2013, to Dec. 13, 2018, to pursue their securities fraud claims as a group. He rejected J&J's argument that any class period be at least a year shorter because some events that allegedly caused its stock price to fall contained no "new" information.

J&J's talc products have included its signature baby powder. The company stopped selling talc-based baby powder globally this year, switching to corn starch as the main ingredient. It has said its talc products are safe and do not contain asbestos.

Vibrating Weight Loss Pill Could Provide Alternative to Ozempic and Wegovy, Researchers Say

Fox News reported:

A vibrating pill has shown promise in early studies as a possible obesity treatment. Developed by engineers at MIT (Massachusetts Institute of Technology), the capsule is intended to be swallowed prior to eating in order to "trick" the brain into thinking the body is full — thereby reducing the amount of calories consumed.

The vibrations activate the "stretch receptors" that detect satiety after eating, sending a signal to the brain that the stomach is full even if it's not.

"This could be really interesting in that it would provide an option that could minimize the side effects that we see with the other pharmacological treatments out there," said lead author Shriya Srinivasan, Ph.D., a former

MIT graduate student who is now an assistant professor of bioengineering at Harvard University.

The capsule, which is about the size of a multivitamin, includes a small oxide battery. After it's swallowed, stomach acids dissolve the casing of the pill and the vibrating motor is activated. The vibrations then activate the receptors that stimulate the vagus nerve, which sends a signal of fullness to the brain.

The researchers aim to test the capsules in human clinical trials in 2024.

The Guardian View on Anti-Obesity Drugs: Treating a Disease That Modernity Made

The Guardian reported:

This might be attractive to those making New Year resolutions that promise improvements in their lives. Weight-loss drugs reveal that obesity is not a deep-seated aspect of character but something more contingent. Obesity is made by modernity, not just poor choices.

The spread of expanding waistlines is driven by sedentary work and the abundance of cheap, high-calorie processed foods. Carrying too much weight causes a host of health problems. The novel treatments raise questions about the type of society we want. The drugs are also not cheap. Healthcare analyst Airfinity says it would cost $1.1m to prevent "one heart attack, stroke, or cardiovascular death" using the weight-loss treatment Wegovy.

More than 70 other obesity treatments are in development, suggesting that costs may drop. Perhaps that's why the U.K. government's anti-obesity measures keep being put off. The trouble is the limited supply. There are, for instance, perpetual shortages of semaglutide, the active ingredient in Ozempic, which was designed to treat a life-threatening disease — type 2 diabetes — but produces startling weight loss. The upshot is that the rich are able to get hold of Ozempic when the ill cannot. British ministers say this is not supposed to happen. But it does.

The new treatments work by mimicking naturally occurring hormones to lower blood sugar, reduce cravings and produce a faster sense of fullness. They might also be transformative in treating many other conditions. But the path from opportunity to cure is a long one. The drugs' side effects include nausea and vomiting. Then there's the risk of regaining weight once off the treatments. Some patients compare the drugs to an opiate addiction.

Novartis, Voyager Launch Another Gene Therapy Mission With $100 Million Upfront Deal

Fierce Biotech reported:

Novartis will launch another gene therapy satellite with Voyager Therapeutics in a $100 million upfront deal to develop candidates in Huntington's disease and spinal muscular atrophy.

The total deal value could rise to a meaty (but heavily back-loaded) $1.2 billion in preclinical, development, regulatory and sales milestones, with royalties down the line, according to a Tuesday press release. Novartis is making a $20 million purchase of newly issued equity in the biotech as part of the deal.

The companies know each other well, having been working together on adeno-associated virus (AAV) capsids since March 2022, with Novartis opting in on two out of three candidates in March 2023. Now, a new deal has been struck to find new approaches for the two devastating diseases.

Indonesia and Mauritania Report Vaccine-Derived Polio Cases

CIDRAP reported:

> Two countries reported new polio cases this week, including Mauritania, which reported its first circulating vaccine-derived poliovirus type 2 (cVDPV2) case of the year, according to the latest weekly update from the Global Polio Eradication Initiative (GPEI).
>
> Indonesia's patient is from Central Java province on the island of Java, and the illness marks the country's fourth such case of the year.

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